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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/972,882	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: On page 4 line 11 in the specification "reaction ration" should be --reaction ratio--.

Appropriate correction is required.

Claim Objections

Claim 4 is objected to for the recitation "a solid phase having binding sites" because a solid phase does not just have binding sites. The binding sites have to be incorporated onto the solid phase. Appropriate correction is required.

Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 is vague and indefinite because there appears to be a correlation step missing for the detection of the analyte. It is unclear how the analyte can be detected without the use of a label.

Claim 1, part (b) "specified fraction" is vague and indefinite. It is unclear what is considered to be a specified fraction, i.e. all of the receptor or a percentage of the amount of receptor (4/4 can be considered a specified fraction). There is no definition of the term provided in the specification. See deficiencies throughout the claims.

Claim 1, part (b) "the amount" there is insufficient antecedent basis for this limitation.

Claim 1, part (d) "the concentration" there is insufficient antecedent basis for this limitation.

Claim 2 "the sample has a high concentration" is vague and indefinite. The sample has a high concentration of what? Further it is unclear what is considered to be a high concentration. There is no definition in the specification for the phrase "high concentration".

Claim 5 "the whole amount" there is insufficient antecedent basis for this limitation.

Claim 5 "the receptor-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 5 "the solid-phase binding capacity" there is insufficient antecedent basis for this limitation.

Claim 5 is vague and indefinite because of the insufficient antecedent problems listed above and also because it is unclear what applicant is trying to do. It is unclear if the receptor-binding capacity of the solid phase is directed to the same target as the solid phase binding capacity of receptor contacted with the sample. Claim 5 has not been treated on art. However, if applicant should amend the claim any art rejection will be made FINAL.

Claim 6 "the amount of the receptor" there is insufficient antecedent basis for this limitation.

Claim 11 "the ratio" there is insufficient antecedent basis for this limitation.

Claim 11 "the total amount of active analyte-binding receptor" there is insufficient antecedent basis for this limitation. Furthermore, "active-analyte binder receptor" there is insufficient antecedent basis for this limitation. Also it is unclear what is meant by active-analyte binder receptor. See deficiencies throughout the claims.

Claim 11 "the range" there is insufficient antecedent basis for this limitation.

Claim 16 "the specific binding partner" there is insufficient antecedent basis for this limitation.

Claim 19 "the receptor-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 19, "the ligand-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 20 "the ratio" there is insufficient antecedent basis for this limitation.

Claim 20 "the receptor-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 20 "the ligand-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 22 "the amount" there is insufficient antecedent basis for this limitation.

Claim 22, the recitation "capable of" is vague and indefinite. Can the second part bind to a specific ligand or not?

Claim 23 "the ratio" there is insufficient antecedent basis for this limitation.

Claim 23 "the amount" and "the total amount" there is insufficient antecedent basis for these limitations.

Claim 24, line 4 "analyte-binding receptor substance" is vague and indefinite. It is unclear what applicant is referring to (i.e. is the substance a reagent?). See deficiencies throughout the claims.

Claim 26 "the ratio" there is insufficient antecedent basis for this limitation.

Claim 26 "the sum" there is insufficient antecedent basis for this limitation.

Claim 26 is vague and indefinite because it appears that the claim was abruptly ended. It appears that part of the claim is missing.

Claim 29 "the ratio", "the amount" and "the total amount" there is insufficient antecedent basis for these limitations.

Claim 30 "the ratio", "the amount" and "the total amount" there is insufficient antecedent basis for these limitations.

Claim 31 "said flow matrix" there is insufficient antecedent basis for this limitation.

Claim 32 "said lateral flow matrix" there is insufficient antecedent basis for this limitation.

Claim 33 "the ratio" there is insufficient antecedent basis for this limitation.

Claim 33 "the receptor-binding capacity" and "the analyte-specific receptor substance" there is insufficient antecedent basis for these limitations.

Claim 33 "receptor substance" is vague and indefinite. It is unclear what applicant is referring to. Further, there is no definition provided for the term in the specification.

Claim 34 "the receptor-binding capacity" and "the ligand-binding capacity" there is insufficient antecedent basis for this limitation.

Claim 35 "the ratio", "the amount" and "the total amount" there is insufficient antecedent basis for these limitations. See also deficiencies in claim 36.

Claim 37 "the ratio", "the sum" and "the range" there is insufficient antecedent basis for these limitations. See also deficiencies in claim 38.

Claim 38 "no more than about 1:20" is vague and indefinite. 1:20 what?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in th United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 4, 6-8, 10, 13, 14, 15, 22, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest et al (EP 0105714).

Forrest et al disclose a method for determining an analyte in a sample. Forrest et al disclose that the method employs the "sandwich" technique involves the use of an excess amount of receptor to the analyte. Forrest et al disclose contacting the sample with labeled antibodies to the antigen (analyte) and a reagent comprising antibodies to the antigen (analyte). Forrest et al disclose immobilized reagents on a solid phase support, separating the solids fraction from the liquid fraction and determining the amount of label in one of the said fractions and, therefrom, the amount of antigen present in the sample (pages 4 and 5) (page 12). Forrest et al disclose that the labeled antibody reagent can carry a chromophore (p. 9, lines 20-21). Forrest et al disclose that the solid support may take the form of particles, beads, wall-coatings on the reaction vessel or an insert of large surface area (abstract). Forrest et al also disclose the use of a kit (page 10). Forrest et al disclose that the labeled and unlabelled antibody reagents may be added in any order, or simultaneously (p. 9, lines 11-17).

6. Claims 1-3, 8-10,13, 14, 16, 17 rejected under 35 U.S.C. 102(e) as being anticipated by Neumann et al (US 6,184,042).

Neumann et al disclose a method for the immunological determination of an analyte in a sample. Neumann et al disclose the use of a heterogeneous sandwich assay in which the soluble antibody and the solid phase antibody are present in an excess relative to the analyte to be determined so that the sandwich complexes can be formed and also detected essentially completely (col 1, lines 35-44). Neumann et al disclose incubating the sample liquid in the presence of a solid phase with at least two receptors capable of binding to the analyte to be determined in which the first receptor is soluble and the second receptor is bound to a solid phase or is capable of binding to a solid phase and the analyte is detected by determining the label in the solid phase or in the liquid phase. Neumann et al disclose that the solid phase is isolated from the liquid phase (col 4, lines 45-55). Neumann et al disclose that the first receptor is an oligomeric antibody or antibody fragment. Neumann et al disclose that the use of this oligomeric antibody reduces the Hook effect and thus allows for the sample to have a high concentration of analyte and allows for performing the assay on undiluted samples (col 1, line 36 – col 2, line 46). Nuemann et al disclose that the first receptor (antibody) comprises a detectable label (col 3, lines 1-27). Neumann et al disclose that the sample is a serum sample (col 7, line 39). Neumann et al disclose that the second receptor is bound to the solid phase and that the second receptor is biotinylated and the solid phase is coated with avidin or streptavidin (col 4, lines 17-19).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 11, 12, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neumann et al (US 6,184,042) in view of Nazareth et al (US 6,319,676).

See above for teachings of Neumann et al.

Neumann et al differ from the instant invention in failing to teach the solid phase binding sites for the receptor are immobilized in a reaction zone of a flow matrix.

Nazareth et al disclose a lateral flow matrix using the sandwich technique in which receptors are immobilized in the reaction zone of the flow matrix (col 1- col 4). Nazareth also disclose predeposited analyte-binding receptor reagent upstream of the reaction zone (col 2, lines 29-52). Nazareth et al disclose the use of immobilized receptors in the flow matrix provides for a rapid, sensitive device and method for detecting the presence of analytes in body fluids and that the method and device have high sensitivity and result in virtually no false positives (col 1, lines 44-50).

It would have been obvious to one of ordinary skill in the art to immobilize the receptors to a solid phase such as taught by Nazareth et al into the method of Neumann et al because Nazareth et al shows that the use of immobilized receptors in the flow matrix provides for a rapid, sensitive device and method for detecting the presence of analytes in body fluids and that the method and device have high sensitivity and result in virtually no false positives.

With respect to the ratios between said isolated fraction of the amount of active analyte-binding receptor ant the total amount of active analyte-binding receptor contacted with the sample and the range values as recited in the instant claims, the optimum ratio and range can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neumann et al in view of Guan et al. (US 6,316,205).

See above for teachings of Neumann et al.

Neumann et al differ from the instant invention in failing to teach the sample is a whole blood sample.

Guan et al disclose a sandwich assay in which the sample is a whole blood sample. The use of such a sample provides for a versatile assay device (col 5, lines 13-29).

It would have been obvious to one of ordinary skill in the art to use a whole blood sample as taught by Guan et al into the method of Neumann et al because Guan et al shows that the use of such a sample provides for a versatile assay device.

10. Claims 19-28 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neumann (US 6,184,042)et al in view of Nazareth (US 6,319,676) and Boguslaski et al (US 5,420,016).

See above for teachings of Neumann et al and Nazareth et al.

Neumann et al and Nazareth et al differ from the instant invention in failing to disclose packaging the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various reagents and components of Neumann et al and Nazareth et al into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator. Furthermore, with respect to the ratio between the amount of ligand-binding analyte-specific receptor and the total amount of analyte-specific receptor as recited in the instant claims, the optimum ratio can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of

workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
August 5, 2002

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08/08/02